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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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WILMINGTON, DE 19899				
EXAMINER				
NGUYEN, BAO THUY L				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/563,681

Applicant(s)

SCHWIND ET AL.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5 and 16-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 6/8/09 & 4/6/09

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08 June 2009 has been entered.

Status of the Claims

2. Claims 1-24 are pending.
3. Claims 4, 5 and 16-24 have been withdrawn.

Claim Rejections - 35 USC § 112, first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3 and 6-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claim 1 recites a device where the indicator zones are located between the application zone and the at least one absorption region and are positioned on the membrane substantially parallel to each other and *absent a physical separator between indicator zones*. This device is not supported by the specification as originally filed. Applicant asserts that support for claims 1-3 can be found in the specification at page 8, line 21 to page 9, however, a careful review of these pages as well as the entire specification does not reveal adequate support for this limitation. Pages 8 and 9 discuss the arrangement of the indicator zones and do not teach a device where the indicator zones are placed parallel to each other and absent a physical separator between them.

In the event that applicant believes support can be found for this limitation, it is respectfully requested that applicant point to the page and line number where such support may be found.

Claim Rejections - 35 USC § 112, second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-3 and 6-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague with respect to the recitation of "the at least two indicator zones comprise at least two types of indicator particles are used of which at least one type being erythrocytes", line 16. It appears that the words "are used" should be removed from this phrase.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-3 and 6-7, 9, 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geisberg (US 6,103,536) in view of Jerome et al (US 6,855,561).

Geisberg teaches a device comprising a single membrane having an application zone, at least one group of indicator zones having reagents appropriate to bind the analytes and at least one absorption region. See column 4, lines 13--38. Geisberg teaches multiple indicator zones for detecting a plurality of analytes and further teaches that for each analyte, a separate series of particulate zones and detection zones can be placed in parallel on one comparatively wide strip. See column 8, lines 12-26.

With respect to claim 3, Geisberg teaches that the indicator zones may be arranged in a linear row.

With respect to claim 6, Geisberg teaches a circular confirmation where the sample receiving zone would be placed at the center of the circle and the indicator zones are arranged in concentric rings radiating from the center. See column 8, lines 26-33.

With respect to claim 7, Geisberg teaches antibodies and other ligands. See column 12, lines 42-55.

With respect to claims 12-15, Geisberg teaches that the solid support can partially or fully be enclosed in a moisture-impermeable, inert casing that can be transparent, translucent or opaque.

See column 10, lines 54-67. Geisberg also teaches a backing to increase handling strength. See column 10, lines 28-42.

Geisberg differs from the instant invention in failing to teach the use of erythrocytes as labels.

However, Jerome teaches labels such as erythrocytes, erythrocyte ghost, colloidal particles and latex beads are functional equivalent. See column 7, line 41 through column 8, line 9.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the labels taught by Jerome in the device of Geisberg because Jerome teaches that these labels are functionally equivalent. A skilled artisan would had a reasonable expectation of success in using substituting the labels taught by Geisberg with those of Jerome because these labels are well known in the art.

10. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geisberg in view of Jerome (US 6,855,561) as applied to claim 1 above, and further in view of Eisinger et al (US 4,943,522).

See the discussion of Geisberg and Jerome above. These references differ from the instant claims in failing to teach the use of antibody or antibody fragments against blood group antigens or antigen epitopes.

Eisinger teaches device and method for detecting blood group antigens. Eisinger teaches reagents for analytes including antigen present on red blood cells. See column 5, lines 37-48. Eisinger teaches methods of blood typing by applying a blood sample to a device having more

than one indicator zones, each of which contains a blood typing reagent. See column 5, lines 60-68.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the antibodies taught by Eisinger in the device of Geisberg as modified by Jerome because Geisberg teaches that its device is appropriate for a variety of analytes with the use of appropriate reagents and Eisinger teaches reagents and method for blood typing as being well known in the art.

11. Claims 1-3, 6-11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang (US 5,559,041) in view of Jerome (US 6,855,561) and Eisinger et al (US 4,943,522).

Kang discloses a device for immunoassay comprising a membrane with an application zone 110, at least two indicator zones 218 and 228 (Figure 4), at least one absorption region 116. Kang teaches that the device comprises at least two different tracks and according to figure 3, they may be in different direction. See also column 4, lines 12-65.

Regarding claim 2, Kang teaches multiple flow tracks. See column 4, lines 38-49.

Regarding claim 3, Kang teaches indicator zones arranged linearly. See the figures.

Regarding claim 6, Kang teaches multiple indicator zones arranged opposite each other. See figure 3.

Regarding claim 7, Kang teaches antibodies or antigens as the labeled binding partners. See example 1.

Regarding claim 11, Kang teaches cellulose membrane. See example 1.

Regarding claim 13, Kang teaches conjugate pad comprising labeled reagents. See example 1.

Regarding claim 14, Kang teaches a plastic backing. See column 11, lines 45-53.

Regarding claim 15, Kang teaches a casing. See figure 4.

Kang differs from the instant claims in failing to teach the use of erythrocytes as labels, and reagents analytes in plasma and cellular bound analyte.

Jerome and Eisinger are discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kang by substituting the labels taught by Kang with the erythrocytes or erythrocytes ghosts as taught by Jerome because the labels of Kang and Jerome are functionally equivalent. It also would have been obvious to include reagents to detect cellular bound analytes and other in plasma samples because Kang teaches that their device is appropriate for detecting multiples analytes and provides the advantage of a one step device capable of detecting multiple analytes from the same sample with minimal involvement from the user.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-3 and 7-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/563,659 in view of Jerome (US 6,855,561).

'659 teaches a device comprising an application zone, at least one group of at least two indicator zones, at least one absorption region and at least two different flow tracks are present.

'659 differs from the instant claims in failing to teach particles comprising erythrocytes.

See the discussion of Jerome above.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of '659 to include erythrocytes as the particles labels as taught by Jerome because Jerome teaches that erythrocytes labels are conventional and well known in the art.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

14. Applicant's arguments with respect to the rejection of claims 1-3 and 7-15 under Hardman in view of May and Eisinger have been considered but are moot in view of the new ground(s) of rejection.

15. The rejection of Klimov and Eisinger are withdrawn in view of the amendment to the claims, therefore, their arguments are moot.
16. The arguments with respect to the rejection of claims 1-3, 6-11 and 13-15 under Kang in view of Eisinger have been considered but are moot in view of the new grounds of rejection.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
June 17, 2009

